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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,294	11/22/2006	Debbie Stevens-Wright	B1075.71016US01	1798
23628 7590 03/25/2010 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206				
EXAMINER				
PEFFLEY, MICHAEL F				
ART UNIT		PAPER NUMBER		
3730				
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03/25/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/551,294

Applicant(s)

STEVENS-WRIGHT, DEBBIE

Examiner

Michael Peffley

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 14-16, 20, 23-25, 27, 30, 38, 91 and 92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 and 6 is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-10, 12, 14-16, 20, 23-25, 27, 30, 38, 91 and 92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 Sept 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-646)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 26, 2010 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1, 2, 9, 10, 12, 14-16, 20, 23-25, 27, 30, 38, 91 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoey et al (6,409,722) in view of the teachings of the articles to Zhang et al ("Noncontact Radio-Frequency Ablation for Obtaining Deeper Lesions") and Jain et al ("A Three-Dimensional Finite Element Model of Radiofrequency Ablation with Blood Flow and its Experimental Validation").

Hoey et al disclose another system that provides various feedback data to control the output of an RF ablation device. Specifically, Hoey et al disclose a flow sensor and an impedance and temperature feedback system to provide feedback to a controller to control the output parameters of the electrosurgical generator. The output power, voltage, current and the flow rate may all be controlled based on sensed conditions (Abstract). Hoey et al fail to teach providing a signal related to the distance of the

ablation electrode from tissue as part of the feedback data used to control the energy output, and also fails to disclose the use of blood flow as a feedback signal.

Zhang et al teach that it is generally known to vary fluid flow rates and energy from the generator based on the distance of the electrode from the tissue being treated (see Abstract). The distance was maintained using spacers to provide a desired distance from the electrode to the tissue in a non-contact ablation procedure. The user would select the desired spacing when setting the output for the generator for the procedure.

As addressed in the previous Office action, Jain et al teach in the article that it is generally known that blood flow provided around a probe effects the cooling of an RF electrode, and that it is advantageous to provide a feedback signal of the blood flow around a probe in order to more accurately control the temperature of an RF probe in the body.

To have provided the Hoey et al system with a spacing element to provide for non-contact ablation of a target tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Zhang et al. To have further provided the specific spacing used as an input to the controller to control the output parameters of the system would have been an obvious consideration, particularly since Zhang et al teach that it is known to vary output parameters based on the fluid flow rate and distance of the electrode from tissue. Further, the use of blood flow as a feedback parameter to control the output of the RF generator would also be an obvious

consideration for the skilled artisan since Jain et al fairly teach it is known to monitor and use such a parameter to control the output of an RF source.

Claims 3, 4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoey et al (6,409,722) in view of the teaching of the articles to Zhang et al ("Noncontact Radio-Frequency Ablation for Obtaining Deeper Lesions") and Jain et al ("A Three-Dimensional Finite Element Model of Radiofrequency Ablation with Blood Flow and its Experimental Validation") and further in view of the teaching of Rittman, III et al ('969).

While it would be intuitive to use algorithms and/or finite element modeling to arrive at the specific relationships between the various feedback parameters and the generator output of the Hoey et al system, there is no express disclosure in Hoey of using such an analysis in generating the output relationships between the generator and the feedback signals.

Rittman, as addressed previously, disclose an analogous RF ablation system that includes a controller that receives various input signals and correlates the input signals into desired output parameters for the RF generator. In particular, Rittman teach of using various algorithms, finite modeling and other relationships for correlating the output parameters of the RF generator to the input signals (col. 14, lines 10-22).

To have provided the Hoey et al system, as modified by the teachings of Zhang et al and Jain et al, with an algorithm or modeling program to correlate the generator output to the received feedback signals would have been an obvious modification for

one or ordinary skill in the art since Rittman fairly teaches it is generally known to use such algorithms and modeling in an analogous system.

Response to Arguments

Applicant's arguments filed February 5, 2010 have been fully considered but they are not persuasive.

The rejection using Rittman et al ('959) as the base reference has been withdrawn in view of applicant's amendments.

Regarding the combination of Zhang et al and Jain et al with the Hoey reference, applicant initially argues at page 8 of the response that Jain does not provide any discussion controlling temperature of an RF probe. The examiner disagrees and respectfully directs applicant's attention to the title of the Jain et al article which describes a model of "Radiofrequency Ablation". Clearly, the Jain et al article is directed to the effects of blood flow on an RF ablation probe. The examiner maintains that this teaching of Jain et al is a relevant suggestion that blood flow around an RF probe would be a relevant feedback parameter in an RF control system, such as taught by Hoey.

Regarding applicant's arguments that the teachings of Jain and Zhang are in conflict, the examiner respectfully disagrees. Applicant is attempting to bodily incorporate the systems disclosed by Jain and Zhang into the Hoey reference. It is not necessary for the examiner to justify such a bodily incorporation of the teaching references. Rather, the examiner must show that there is proper suggestion in the teaching references to suggest to one of ordinary skill in the art that the combination of

teachings is tenable. Hoey discloses a non-contact probe that provides fluid to the treatment area, and provides feedback related to various different parameters to control the output of the RF generator. Zhang specifically teaches that the distance from which a probe is separated from tissue during a non-contact procedure affects the lesion characteristics. See, specifically, page 221, section B ("Lesion Dimensions Versus Distances"). Hence, Zhang provides a relevant teaching that the particular distance a probe is from tissue is a relevant parameter that may be monitored to more effectively control the procedure. The examiner maintains that this teaching seamlessly combines with the Hoey reference as another potential feedback parameter that one of ordinary skill in the art would consider in an RF control system. Similarly, Jain provides the relevant teaching that blood flow may also impact the performance of an RF electrode and may be a parameter of interest in an RF control system. While Jain may briefly discuss the probe as being in contact with tissue, there is no requirement that the probe must be used in that capacity to effect operation of the RF electrode device. The examiner maintains that one of ordinary skill in the art would recognize from Jain that blood flow surrounding the probe is a parameter that may be used in a feedback mechanism to properly control the heating of an RF electrode, and that such a parameter would be applicable to a device used in either a contact or a non-contact mode. It is noted that the Hoey probe is used in cardiac procedures and intravascular procedures and would be used in environments subjected to blood flow.

Allowable Subject Matter

Claims 5 and 6 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
March 24, 2010